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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,799	04/13/2004	Ferdinand Haschke	88265-16764	3045

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BELL, BOYD & LLOYD LLC
P. O. BOX 1135
CHICAGO, IL 60690-1135

EXAMINER	
TONGUE, LAKIA J	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 09/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/822,799	HASCHKE ET AL.	
	Examiner	Art Unit	
	Lakia J. Tongue	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-19* is/are pending in the application.

4a) Of the above claim(s) *3* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 4-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's response filed on July 1, 2005 is acknowledged. Claims 1, 2 and 4-19 are pending and under consideration. Claim 3 has been canceled and withdrawn from consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

Objections Withdrawn

2. In view of applicant's response, the objections to the specification and for priority on page 2 are withdrawn.

3. In view of applicant's response the objection over claim 14 is withdrawn.

Rejections Withdrawn

4. In view of applicant's response, the rejection to claims 1, 4-6, 8-9 and 11-13 under 35 U.S.C. 103 on page 5, paragraph 5 is withdrawn.

Rejections Maintained

Please note that the following rejection is maintained over claims 2,15-17 and 19 for the reasons set forth below in addition to claims 1,4-14 and 18.

5. The rejection of claims 1-19 under 35 U.S.C 112, first paragraph, (scope of enablement). The above rejection is maintained for the reasons set forth in the previous Office Action page 3.

The rejection was on the ground that Claims 1- 19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of enhancing immune response to the measles virus after a measles vaccination by administering to a subject a prebiotic or nutritional composition, does not reasonably provide enablement for a method of enhancing an immune response by administering a prebiotic to prevent or treat measles before a measles vaccination or for a prebiotic to prevent or treat the measles alone or in combination with a probiotic. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The examiner interprets the claims as a method of enhancing an immune response by giving a prebiotic alone or in combination with a probiotic. Applicant is not enabled for the method wherein at least one prebiotic or nutritional composition comprising at least one prebiotic is administered to a subject for prevention or treatment of measles without administration of a measles vaccination. The specification teaches that an improved immune response did occur after the regular consumption of a composition with a prebiotic, but only after a measles vaccination (p.6). Prebiotics and probiotics are known in the art to enhance immune response, however there is no correlation between prebiotics, probiotics or the combination of the two and the treatment or prevention of the measles.

Factors to be considered in determining whether a disclosure would require undue experimentation have been reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CRFC1988). The Wands factors to be considered are:

a. the quantity of experimentation necessary,
b. the amount of direction or guidance presented,
c. the presence or absence of working examples;
d. the nature of the invention;
e. the state of the prior art;
f. the relative skill of those in the art;
g. the predictability or unpredictability of the art;
h. breadth of the claims.

The presence or absence of working examples utilizing the administration of a prebiotic alone or in combination with probiotics for the treatment and or prevention of measles are exemplified in the instant specification, however it is not clear that results were obtained as suggested. The prevention and/or treatment of measles were not achieved. The examples provided disclose an immune enhancement, but only after measles vaccination is administered. The quantity of experimentation necessary would be undue for the utilization of any prebiotic or nutritional composition administered to a subject for prevention and/or treatment of measles. The specification lacks guidance with respect to the utilization of prebiotics for the treatment and/or prevention of the measles. The amount of direction or guidance presented is minimal in terms of working examples. The nature of the invention involves treatment of the measles with any prebiotic and without any evidence to the contrary, could result in the subject not having protection against measles or treatment of measles, which could result in damage to the patient. The state of the prior art describes the following: Firmansyah, A. et al ("Improved Humoral Immune Response To Measles Vaccine In Infants Receiving Infant Cereal With Fructooligosaccharides", Journal of Pediatric Gastroenterology and Nutrition, 2000; 31) discloses a double-blind randomized controlled study to examine the effects on the immune response after measles vaccination of an infant cereal supplemented with a prebiotic mixture of fructooligosacchardes and inulin. The results concluded that regular consumption of infant cereals with the prebiotic mixture improves immune response after measles vaccination. Agostoni, C. et al (Prebiotic Oligosaccharides in Dietetic Products for Infants: A Commentary by the ESPGHAN Committee on Nutrition, 2004; 39: 465-473) state that future trials should define optimal quantity and types of oligosaccharides with prebiotic function, optimal dosages and duration of intake. Short and long term benefits and safety. At the present time the committee takes the view that no general recommendation on the use of oligosaccharide supplementation in infancy as a prophylactic or therapeutic measure can be made (abstract, page 465). Agostoni et al suggest that the use of prebiotics might lead to increased resistance to pathogens (mainly gastrointestinal tract pathogens), modulation of the systematic immune response and of allergic risk, improved bowel function and laxative effects, reduced risk of colon cancer, reduction in cholesterol and blood lipids and enhanced calcium bioavailability and bone mineralization (column 1, page 467). Agostoni et al also disclose that there is no beneficial clinical effect of prebiotics added to infant formulae other than

an effect on stool frequency and consistency (column 2, page 467 and column 1, page 468). Agostoni et al conclude that currently there are only limited published data on the evaluation of prebiotic substances in dietetic products for infants. Further, Roberfroid, M. (Prebiotics and probiotics: are they functional foods?, Am J Clin Nutr, 2000; 71: 1682s-7s) claims that inulin-type fructans reduce the risk of disease are only tentative and still need to be supported and validated by further research. The claims include: constipation relief, suppression of diarrhea, reduction risk of osteoporosis, reduction of the risk of atherosclerotic and cardiovascular disease. Cancer is the last area of further research (column 2, page 1684s and column 1, page 1685s). Roberfroid states that the only areas where evidence can be considered promising are diarrhea (probiotics) and constipation (prebiotics) (column 2, page 1685s). Lastly, Roberfroid suggest that the combination of probiotics and prebiotics could beneficially affect the host by improving survival and implantation of live microbial dietary supplements in the gastrointestinal flora and improve the survival of the bacteria crossing the upper part of the gastrointestinal tract (coulmn1, page 1686s). The relative skill in the art is recognized as high. The breadth of the claims is broad to include oligosaccharide, glucose, galactose, xylose, maltose, sucrose, lactose, starch, xylan, hemicellulose, inulin, or a mixture thereof. Therefore, in view of all of the above and in view of the state of the art, it is determined that it would require undue experimentation to use the invention commensurate in scope with the claimed subject matter.

Applicant urges that a) claim 19 has been amended to depend from allowed claim 18, b) claim 3 has been canceled and c) claims 2 and 15 have been amended to recite, in part, "a method of enhancing an immune response where the prebiotic is present in an amount sufficient to enhance a measles immune response".

It is the examiner's position that applicant has neglected to show enablement for the enhanced immune response and that applicant is only enabled for a method of enhancing an immune response to the measles virus **after** a measles vaccination has been administer followed by administering to a subject a prebiotic or nutritional composition, thereby enhancing an immune response.

It has been stated that claim 18 is free of the prior art, however the method steps of claims 1 and 2 are not the same as that of claim 18. The difference being that there is no measles vaccine used in claims 1 or 2. The examiner cannot decipher from the examples provided whether or not the response recorded in example 1 is specific to the measles. There has not been any other example provided to show that the claimed enhanced immune response is indeed that of the measles virus. If no measles vaccine

were administered to a subject, would the subject still get a measles immune response? What is the population of the subjects involved in this study?

Additionally, claims 18 and 19 are enabling for a method for preventing measles by enhancing an immune response which comprises administering a first measles vaccine to a subject and administering at least one prebiotic or nutritional composition comprising at least one prebiotic to the subject, wherein the prebiotic is present in an amount sufficient to enhance a measles immune response. However, the claims do not reasonably provided enablement for a method of treating the measles. The specification does not provide an adequate showing of treating a subject wherein the disease already exists.

Response to Arguments

6. Applicant's arguments filed 7/1/05 have been fully considered but they are not persuasive. In so far as applicant's traversal is applicable to the 35 U.S.C. 102(e) below the examiner is addressing the arguments. Applicant urges that a) Vesely et al fails to disclose or suggest all of the claimed elements, b) Vesely et al fails to disclose or suggest administering at least one prebiotic, wherein the prebiotic is present in an amount sufficient to enhance an immune response and c) Vesely et al fails to recognize a method for enhancing an immune response by administering prebiotics, offers no details about it and offers no experiments to show that administering prebiotics enhances the immune response as the Applicant's have done.

It is the examiner's position that the claims are drawn to a method of enhancing an immune response which comprises administering at least one prebiotic or nutritional composition comprising at least one prebiotic, wherein the prebiotic is present in an amount sufficient to enhance an immune response. The method of Vesely et al is the same as the instantly claimed method. The instant specification disclose that the most preferable prebiotic is a mixture of fructo-oligosaccharide and inulin sold under the trademark PREBIO1® or a mixture of oligofructose sold under the trademark RAFTILOSE® (page 2). The prior art teaches appropriate oligosaccharides to be inulin and inulin-oligofructose sold under the trademark Raftline™ and Raftilose™ respectively (column 4, lines 60-64). The preferred trademarked composition would inherently have the prebiotic present in an amount sufficient to enhance an immune response since it is the same trademarked product which applicant utilizes to execute the present invention. Moreover, Vesely et al teaches a method of administering the claimed composition to stimulate an immune response (column 7, lines 56-64). The examiner is holding "stimulate" analogous to "enhance" (see attached). Lastly, "Vesely et al teaches,

and discloses the present claims as the limitations of the claims have been met because Cavaliere Vesely et al teaches a method of enhancing an immune response by administering the composition by consuming a composition which contains at least one prebiotic.

Applicant's arguments with respect to claims 1, 4-6, 8-9 and 11-14 have been considered but are moot in view of the new ground(s) of rejection.

New Grounds of Rejection

Specification

7. The disclosure is objected to because of the following informalities: on page 2 line 22 the word "forth" should be replaced with the word fourth.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1, 4-6, 8-9 and 11-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Cavaliere Vesely et al (U.S. Patent 5,895,648).

Claims 1, 4-6, 8-9 and 11-14 are drawn to a method of enhancing an immune response which comprises administering at least one prebiotic or nutritional composition comprising at least one prebiotic, wherein the prebiotic is present in an amount sufficient to enhance an immune response.

Cavaliere Vesely et al discloses a method of enhancing an immune response by administering the composition by consuming a composition which contains a mixture of

lyophilized live bacteria comprising at least two species of bacteria selected from *Bifidobacterium breve, Bifidobacterium infantis, Bifidobacterium longum,* and *Bifidobacterium bifidum* and at least two species of bacteria selected from *Lactobacillus acidophilus, Streptococcus thermophilus; Lactobacillus bulgaricus, Lactobacillus casei, Lactobacillus plantarum* and*Streptococcus faecium* and one or more oligosaccharides (abstract); (oligosaccharide = prebioitc, taught by instant specification page 2, lines 28-33). Moreover, Cavaliere Vesely et al disclose that suitable oligosaccharides include oligofructose, galacto-oligosaccharides and soybean-oligosaccharides among others (column 4, lines 53-59). Particularly the appropriate oligosaccharides are inulin and inulin-oligofructose, which are marketed under the names Raftline™ and Raftilose™ (column 4, lines 60-64). Cavaliere Vesely et al disclose that the composition may also consist of sugar and may be added to consumables such as liquid, creamy or pasty foodstuffs, products of the milk and dairy industry (milk, milk-based products, milk derivatives) (column 6, lines 55-60). For example, the composition of the present invention can be added to a milk type, yoghurt, or another type of fermented milk, milk based dessert, milk based beverage or a beverage based on milk serum or permeate enriched with fruit, a fruit juice or a beverage based on vegetable extractions (column 6, lines 15-23). Moreover, Cavaliere Vesely et al discloses that the object of the present invention is to provide supplementation by having the foodstuff consumed (column 6, lines 1-8). Cavaliere Vesely et al disclose that the present invention is very useful because it promotes the human organism welfare, promotes synthesis of vitamins and proteins, facilitates digestive processes, prevents colonization and stimulates the

immune response (column 7, lines 56-64). The instant specification teaches that a clear advantage of a nutritional product is that it may be administered orally (page 3, lines 19-25). OneLook Dictionary Search defines the term "consumed" as eaten or drunk up (see attachment). In view of the definitions recited above the method of Cavaliere Vesely et al is the same as the claimed method.

Since the Office does not have the facilities for examining and comparing applicants' composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakia J. Tongue whose telephone number is 571-272-2921. The examiner can normally be reached on Monday-Friday 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LJT

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600